

REMARKS

After entry of this Amendment, the pending claims are: claims 1-3, 5-15, 19-32 and 34. The Final Office Action dated June 11, 2008 has been carefully considered. Claim 33 has been canceled. Claims 4 and 16-18 were previously canceled. Claims 1, 19 and 32 have been amended. Support for the amendments to claims 1, 19 and 32 can be found throughout the Specification and Drawings and specifically in paragraph Nos. 27, 28, 58 and 59 and Fig. Nos. 6a, 6b, 7a and 7b. Accordingly, no new matter has been added to the application as a result of the described amendments to the claims. Reconsideration and allowance of the present application in view of the above Amendments and the following remarks is respectfully requested.

In the Final Office Action dated June 11, 2008, the Examiner rejected claims 1-3, 5-15 and 19-34 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,706,068 to Ferree ("Ferree") in view of U.S. Patent No. 6,106,557 to Robioneck et al. ("Robioneck").

INDEPENDENT CLAIM 1

Independent claim 1 and claims 2, 3 and 5-15 have been rejected as being unpatentable over Ferree in view of Robioneck. Specifically, the Examiner indicates Ferree discloses each and every limitation of independent claim 1 but for the outermost ends of the articulating parts being removable within an oval recess formed in at least one of the connecting elements. That is, as admitted by the Examiner, Ferree does not disclose a recess fitted with an axially terminal cavity formed in at least one of the connecting elements and an adjoining outermost end of an adjacent articulating part comprising a widening wherein the widening is insertable into the cavity so that said at least one articulating part is slidably displaceable, in situ, with respect to

said adjoining connecting element. Rather, the Examiner relies on Robioneck for disclosure of a removable connection element. According to the Examiner, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the implant disclosed in Ferree with a removable connection element as disclosed in Robioneck. Applicants respectfully traverse this rejection with respect to the above-listed claims, as amended.

Referring to Figs. 1-13B, Ferree, at best, discloses a two-piece articulating implant wherein the implant includes superior and inferior end plates. Each of the endplates includes an integral bone contacting surface and an articulating surface.

Referring to Figs. 1-5, Robioneck discloses a cage-like fusion implant comprising one or more middle bodies 10 as well as two end bodies 14, 16. The end bodies 14, 16 are engageable to vertebra body plates 18, 20, respectively. The end bodies 14, 16 include a dovetail guide for engaging runners formed on the plates 18, 20. The fusion implant is sized and configured such that following connection to the vertebra, the middle bodies 10, the end bodies 14, 16 and the vertebra body plates 18, 20 are securely anchored with respect to one another. The middle bodies 10 and the end bodies 14, 16 include teeth such that when the middle bodies 10 and the end bodies 14, 16 are stacked onto one another, the teeth interlock with one another thus providing further stabilization. Thus, Robioneck discloses a stacked, modular fusion implant that prevents movement following implantation.

Applicants respectfully submit that any combination of Ferree in view of Robioneck would still not disclose each and every limitation of independent claim 1. Amended claim 1 is directed to an intervertebral implant and recites, *inter alia*, as follows:

(A) two articulating parts each having a central axis, each having a slide surface intersecting the central axes and each having an outermost end, wherein: (B) the slide surfaces are curved, (C) the slide surfaces are mutually displaceable, and (D) the second articulating part is rotatable about two skewed axes of rotation relative to the first articulating part, wherein the axes of rotation are spaced apart from one another by a distance A that is between about 0.1 to 20 mm, (E) the outermost ends of the articulating parts each comprise a connection element, wherein: (F) at least one of the connecting elements is fitted with an oval recess coaxial with the central axis, the at least one oval recess being sized and configured to receive one of the outermost ends of the adjoining articulating part; wherein: (G) **the recess is fitted with an axially terminal cavity, the axially terminal cavity having a diameter and the adjoining outermost end of the adjacent articulating part comprises a widening coaxial with the central axis, the outermost end having a diameter, the diameter of the axially terminal cavity being larger than the diameter of the outermost end, said widening being insertable into the cavity so that said at least one articulating part is slidably displaceable, in situ, with respect to said adjoining connecting element, and (H) the slide surfaces are saddle-shaped having a compound radius with at least two inflection points. (emphasis added).**

As an initial matter, the Examiner is thanked for the courtesy extended during the Examiner Interview held on October 3, 2008. Per the discussion between the Examiner and the Undersigned during the Interview, independent claim 1 is not directed to a removable connection as interpreted by the Examiner. Rather, as best shown in Figs. 6a-7b, the at least one connection element includes a recess formed in the connection element so that the adjacent articulating part can move even after the implant has been implanted.

Therefore, as discussed during the Interview, Applicants respectfully submit that there is no disclosure, teaching, or suggestion in either Ferree or Robioneck of a recess formed in at least one of the connecting elements and the adjoining outermost end of the adjacent articulating part comprising a widening. The recess is fitted with an axially terminal cavity having a diameter and the adjoining outermost end has a diameter. The diameter of the axially terminal cavity is

larger than the diameter of the outermost end so that when the widening is inserted into the cavity the at least one articulating part is slidably displaceable, in situ, with respect to the adjoining connecting element. In contrast, Ferree discloses a two-piece articulating implant incorporating a saddle-shaped slide surface and Robioneck discloses a modular fusion implant wherein the end bodies include a dovetail guide for receiving endplates. Thus, it is respectfully submitted that neither Ferree nor Robioneck, either alone or in combination, discloses, teaches or suggests all of the limitations of independent claim 1 because neither of these references include the claimed diameter of the axially terminal cavity being larger than the diameter of the outermost end so that the articulating part is slidably displaceable, in situ, with respect to the adjoining connecting element. Withdrawal of this rejection and allowance of independent claim 1, as amended, is respectfully requested.

Furthermore, as claims 2, 3 and 5-15 all depend from independent claim 1, it is respectfully submitted that these claims are equally allowable for at least this reason. Allowance of claims 2, 3 and 5-15 is also respectfully requested.

INDEPENDENT CLAIM 19

Independent claim 19 and claims 20-31 have been similarly rejected as being unpatentable over Ferree in view of Robioneck. Applicants respectfully traverse this rejection with respect to the above-listed claims, as amended.

Applicants respectfully submit that any combination of Ferree in view of Robioneck would still not disclose each and every limitation of independent claim 19. Amended claim 19 is directed to an intervertebral implant for implantation between first and second vertebra and recites, *inter alia*, as follows:

a first end plate having an inner side and a first bone contacting surface, said first bone contacting surface being sized and configured to contact said first vertebra; a second end plate having an inner side and a second bone contacting surface, said second bone contacting surface being sized and configured to contact said second vertebra; a first member having a first end and a second end, said first end being sized and configured to contact said first end plate, said second end having a first saddle-shaped contact surface having a compound radius with at least two inflection points; and a second member having a first end and a second end, said first end being sized and configured to contact said second end plate, said second end having a second saddle-shaped contact surface for contacting said first saddle-shaped contact surface of said first member, said first and second saddle-shaped contact surfaces being sized and configured to permit said first member to articulate with respect to said second member along said first and second saddle-shaped contact surfaces; **wherein said inner side of said first end plate includes a recess, the recess having a diameter and said first end of said first member has a diameter, the diameter of the recess being larger than the diameter of the first end of the first member so that said first member is receivable within said recess and moveable with respect to said first end plate even after implantation.** (emphasis added).

Similar to independent claim 1 above, Applicants respectfully submit that there is no disclosure, teaching, or suggestion in either Ferree or Robioneck of a recess formed in the inner side of the first end plate for receiving the first end of the first member, wherein the recess has a diameter and the first end of the first member has a diameter such that the diameter of the recess is larger than the diameter of the first end of the first member. The difference in the diameters permits the first end of the first member to be received within the recess and to be moveable with respect to said first end plate after implantation.

As discussed during the Examiner Interview held on October 3, 2008, independent claim 19 is not directed to a removable connection as interpreted by the Examiner. Rather, as best shown in Figs. 6a-7b, the first end plate includes a recess for receiving the first end of the first member so that the first end of the first member is moveable with respect to said first end plate even after implantation. At best, Ferree discloses a two-piece articulating implant incorporating

a saddle-shaped slide surface. Robioneck discloses a modular fusion implant wherein the end bodies include a dovetail guide for receiving endplates.

Thus, it is respectfully submitted that neither Ferrec nor Robioneck, either alone or in combination, discloses, teaches or suggests all of the limitations of independent claim 19 for at least this reason. Withdrawal of this rejection and allowance of independent claim 19 is respectfully requested.

Furthermore, as claims 20-31 all depend from independent claim 19, it is submitted that these claims are equally allowable for at least this reason. Allowance of claims 20-31 is also respectfully requested.

INDEPENDENT CLAIM 32

Independent claim 32 and claims 33 and 34 have been similarly rejected as being unpatentable over Ferree in view of Robioneck. With respect to claim 33, which has been canceled, this rejection is believed to be moot. Applicants respectfully traverse this rejection with respect to the remaining, above-listed claims, as amended.

Applicants respectfully submit that any combination of Ferree in view of Robioneck would still not disclose each and every limitation of independent claim 32. Amended claim 32 is directed to an intervertebral implant for implantation between first and second vertebra and recites, *inter alia*, as follows:

a first end plate having an inner side and a first bone contacting surface, said first bone contacting surface being sized and configured to contact said first vertebra; a second end plate having an inner side and a second bone contacting surface, said second bone contacting surface being sized and configured to contact said second vertebra; a first member having a first end and a

second end, said first end being sized and configured to contact said first end plate, said second end having a first saddle-shaped contact surface having a compound radius with at least two inflection points; and a second member having a first end and a second end, said first end being sized and configured to contact said second end plate, said second end having a second saddle-shaped contact surface having a compound radius with at least two inflection points, for contacting said first saddle-shaped contact surface of said first member, said first and second saddle-shaped contact surfaces being sized and configured to permit said first member to articulate with respect to said second member along said first and second saddle-shaped contact surfaces; **wherein said inner side of said first end plate includes a recess, the recess having an oval shape and a circumferential shoulder and said first end of said first member has a substantially circular shape and is receivable within said recess so that said first member is slidably displaceable, in-situ, in a first direction with respect to said first end plate but not in a second direction.** (emphasis added).

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in either Ferree or Robioneck of a recess formed in the inner side of the first end plate for receiving the first end of the first member, wherein the recess has an oval shape and a circumferential shoulder. Further, Applicants respectfully submit that there is no teaching, suggestion or disclosure in Ferree or Robioneck of the first end of the first member having a substantially circular shape so that the first end of the first member is receivable within the recess and slidably displaceable, in-situ, in a first direction with respect to said first end plate but not in a second direction, as is claimed in amended claim 32.

As discussed during the Examiner Interview held on October 3, 2008, independent claim 32 is not directed to a removable connection as interpreted by the Examiner. Rather, as best shown in Figs. 7a-7b, the first end plate includes an oval shaped recess for receiving the substantially circular shaped first end of the first member so that the first end of the first member is slidably displaceable, in-situ, in a first direction with respect to said first end plate but not in a second direction. At best, Ferree discloses a two-piece articulating implant incorporating a

saddle-shaped slide surface while Robioneck discloses a modular fusion implant wherein the end bodies includes a dovetail guide for receiving endplates.

Thus, Applicants respectfully submit that neither Ferree nor Robioneck, either alone or in combination, discloses, teaches or suggests all of the limitations of independent claim 32 for at least this reason. Withdrawal of this rejection and allowance of independent claim 32 is respectfully requested.

Furthermore, as claim 34 depends from independent claim 32, it is submitted that claim 34 is equally allowable for at least this reason. Allowance of claim 34 is also respectfully requested.

CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 1-3, 5-15, 19-32 and 34, is in condition for allowance and such action is respectfully requested.

A fee of \$810.00 is believed due for this submission for the filing of a Request for Continued Examination. A fee of \$130.00 is believed due for this submission for the filing of a one month extension of time. The Commissioner is authorized to charge these and any other fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

Date: October 13, 2008

Respectfully submitted,

/Giuseppe Molaro/
Giuseppe Molaro
Registration No. 52,039

For: Brian M. Rothery
Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, New York 10038
(212) 806-6114